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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 13

Application Number: 09467903
Filing Date: 12/21/99
Appellant(s): Hosokawa et al.

Lee Cheng
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 9/7/2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of the invention contained in the brief is not correct. The summary refers to the disclosure in the specification of the use of "antibody fragments" in the instant invention. The specification does not disclose use of antibody fragments for the reasons elaborated in the new matter rejection under 35 USC 112 first paragraph elaborated in this Examiners Answer.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims.

Claims 30-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "antibody fragment" in claims 30,35,40 or 45. The scope of the term "antibody fragment" encompasses compositions containing antibody fragments not disclosed in the specification (eg. such as Fv or Fd or $F(ab)_2$). There is no written description in the specification as originally filed of the claimed conjugate or composition containing said conjugate wherein the conjugate contains a " antibody fragment " per se. The scope of the term "antibody fragment" as recited in the claim encompasses conjugates or compositions containing said conjugates wherein antibody fragments not disclosed in the specification (eg. such as Fv or Fd or $F(ab)_2$) are used. There is also no support in the specification as originally filed for the recitation of "$F(ab')_2$" in claims 34,39,44 or 49. The specification, pages 11 and 12, discloses the use of Fab' derived from $F(ab')_2$ for the preparation of the claimed invention, but there is no disclosure of the use of $F(ab')_2$ in the claimed invention. The specification merely discloses the use of $F(ab')_2$ to prepare Fab', wherein the Fab' are then used in the claimed invention. Similarly, there is no

disclosure in the specification as originally filed of conjugates containing "fragments thereof" or conjugates containing antibody fragments that are encompassed by said term (eg. Fd or Fv). There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter).

(11) Response to Argument

Claims 30-49 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in section (10). Appellants arguments have been considered and deemed not persuasive.

Regarding the declarations filed by Hosokawa and Tagawa, and appellants comments in paragraph one and two, page 6 of the instant Brief, the issue under consideration is not one of enablement, it is whether the limitations referred to in the instant rejection constitute new matter. There is still no disclosure in the specification as originally filed of the scope of the claimed invention using antibody fragments per se or $F(ab')_2$. While such fragments and conjugates were known in the prior art, there is no disclosure in the specification as originally filed that such fragments were used in the claimed invention. Regarding applicants comments about $F(ab')_2$, the specification, page 11 and 12 discloses use of Fab' in the instant invention and the use of $F(ab')_2$ to prepare Fab' wherein the Fab' are used in the instant invention, but

does not disclose use of $F(ab')_2$ in the instant invention. $F(ab')_2$ and Fab' are art known fragments of antibodies. The fact that the specification discloses use of $F(ab')_2$ to prepare Fab' is not a disclosure of the use of $F(ab')_2$ in the instant invention. It is merely the disclosure of the use of $F(ab')_2$ as an intermediate product for the production of Fab' which are used in the instant invention. The only antibody fragment disclosed in the specification for use in the instant invention is Fab'. Regarding appellants comments in the Brief, page 7, the specification, pages 11 and 12, the "first method(1)" refers in the specification to a method for use in thiolation of an intact antibody (eg. see page 12, line 3). It does not disclose that said method is practiced with a $F(ab')_2$ or antibody fragment. In addition, the Traut et al. reference to which applicant refers to discloses thiolation of intact protein. Regarding Wright et al., page 351 of said reference does not disclose use of $F(ab')_2$ in antibody conjugates. It discloses use of $F(ab')_2$ as an intermediate product for the production of Fab' which are used in an antibody conjugate and discloses in Table 2 methods for introducing thiols into intact antibodies. Furthermore, neither the Traut et al. or Wright et al. references are disclosed in the specification. The specification, page 12, line 3 refers to a method for thiolation of an antibody. It does not disclose that said method is used for thiolating an $F(ab')_2$. Regarding the specification, pages 1,3,12,36,37,41, said pages do not disclose use of antibody fragments or $F(ab')_2$ in the claimed invention. The specification, pages 36 and 37 disclose production of $F(ab')_2$ which are used to produce Fab', wherein the Fab' are used in the claimed invention. The fact that the specification discloses use of $F(ab')_2$ to prepare Fab' is not a disclosure of the

use of $F(ab')_2$ in the instant invention. It is merely the disclosure of the use of $F(ab')_2$ as an intermediate product for the production of Fab' which are used in the instant invention.

Regarding the term "antibody fragment" as recited in the claimed invention, the term antibody fragment encompasses the use of a variety of art known fragments (eg. Fv, Fd, $F(ab')_2$, etc). There is no disclosure in the specification as originally filed of the use of "antibody fragments" per se in the specification. While the specification discloses use of Fab' in the instant invention, the term "antibody fragment" encompasses antibody fragments such as Fv and Fd which are not even disclosed in the specification. The written description provided in the specification is not commensurate in scope with the claimed invention.

Regarding appellants comments in pages 8 and 9 of the instant Brief, appellants are arguing why the instant invention is obvious in view of the specification and the prior art. There is no disclosure in the specification of the term "antibody fragment". There is no disclosure in the specification of the use of $F(ab')_2$ in the claimed invention. Appellants arguments are essentially drawn to the issue of why the claimed invention is obvious based on the disclosure of the specification and the prior art. However, the CAFC opined in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that written description of an invention extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.. . . "), the specification must contain an equivalent description of the claimed subject matter. A

description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

There is simply no written description in the specification of the use of antibody fragments per se or $F(ab')_2$ in the claimed invention. The specification does disclose use of Fab' in the claimed invention. However, Fab' is only one of a variety of art known antibody fragments. The specification discloses use of F(ab')2 to make Fab', but does not disclose use of F(ab')2 in the claimed invention. Appellants arguments are that the other types of fragments are known in the art and therefore it would have been obvious to use them in the claimed invention. However, as disclosed above, obvious to use is not the standard regarding issues of new matter. Furthermore, assuming arguendo that obviousness was the standard for new matter, it would still not be clear from the record whether appellant did or did not intend to claim the use of antibody fragments or F(ab')2 in the claimed invention because is not clear as to whether at the time of the filing of the intact invention that appellants simply were not interested in the claimed invention that used f(ab')2 or antibody fragments per se, or whether they believed that Fab' fragments possessed particular properties that rendered said fragments useful wherein other fragments did not have said properties or whether it was simply an omission.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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